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Producers of Quality Nonprescription Medicines and Dietary Supplements for Self-Care

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

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Re: [Docket No. 02N-0209], **Request for Comment on First Amendment Issues**, 67 Fed. Reg. 34942 (May 16, 2002)

These comments are submitted on behalf of the Consumer Healthcare Products Association in response to the May 16th *Federal Register* Notice requesting industry submissions with respect to the agency's regulations, guidance, policies and practices in light of the First Amendment. [Docket No. 02N-0209], 67 Fed. Reg. 34942 (May 16, 2002).

Although the May 16th *Federal Register* Notice raises a number of specific questions as to the policy justifications underlying FDA's speech-related regulations, the underlying motivation that pervades this request for comments is the tension between the First Amendment's protection of commercial speech, including the "need and right of Americans to speak and hear information vital to their everyday lives," and the mandate of FDA to "ensure that people are not misled." 67 Fed. Reg. at 34943. Even as the courts have recognized and validated FDA's authority to protect public health and safety and to prevent consumer confusion by regulating the marketing, advertising and labeling claims of FDA-regulated products, the courts have also become increasingly conscious of that tension with the First Amendment.

As FDA takes this opportunity to consider the ways in which its regulation of commercial speech should be balanced with First Amendment protections, CHPA welcomes the opportunity to highlight specific issues for the agency with respect to the regulated products we represent.[1]

[1] CHPA is a 121-year-old trade association representing manufacturers and distributors of over-the-counter medicines and dietary supplements. Its membership comprises over 200 companies across the manufacturing, distribution, research, supply and advertising sectors of the self-care industry.

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Below are several areas in which recent FDA activities with respect to commercial speech affecting over-the-counter (OTC) drugs and dietary supplements have raised Constitutional concerns in light of evolving First Amendment jurisprudence.

I. Application of the First Amendment to FDA Regulation of Labeling and Advertising of OTC Medicines and Dietary Supplements.

There is no question that communications to consumers about over-the-counter medicines and dietary supplements for self-care are constitutionally protected forms of commercial speech and, as such, are entitled to a degree of First Amendment protection. The Supreme Court has repeatedly held that commercial speech, even that expression related solely to the economic interests of the speaker and its audience, is entitled to protection from unwarranted government restriction. Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y., 447 U.S. 557 (1980). Commercial expression not only serves the economic interest of the speaker, but also assists consumers and furthers the societal interest on the fullest possible dissemination of information. *Id.* at 562. The Court has noted that, "It is a matter of public interest that [economic] decisions in the aggregate be intelligent and well-informed." Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 765 (1976).

First Amendment jurisprudence for commercial speech does not distinguish among the type of product or service being promoted by the commercial expression, withholding constitutional protection only from that speech which concerns unlawful activity or which is misleading. Thompson v. Western States Medical Center, 122 S. Ct. 1497, 1504 (2002). The Court has noted that a "particular consumer's interest in the free flow of commercial information . . . may be as keen, if not keener by far, than his interest in the day's most urgent political debate." *Id.* at 1503, *quoting* Virginia Bd. of Pharmacy, 425 U.S. at 763. Given that recognition, it would appear that the availability of truthful and non-misleading information in the context of one's healthcare choices would be especially critical to one's decision making, and therefore especially deserving of a free flow of information. Thus, it is undeniable that commercial speech protection extends to drugs and dietary supplements regulated by the FDA. *See, e.g.*, Western States, 122 S. Ct. at 1504 (invalidating restrictions on advertising of compounded drugs), Virginia Bd. of Pharmacy, 425 U.S. 748 (invalidating restrictions on advertising by pharmacists), Pearson v. Shalala, 164 F.3d. 650 (D.C. Cir. 1999) (affording First Amendment protection to dietary supplement claims).

Just as the First Amendment may prevent the government from prohibiting speech, the First Amendment may also prevent the government from compelling individuals to express certain views. United States v. United Foods, Inc., 121 S. Ct. 2334 (2001). Indeed, the courts have established that compelled product or package labeling, including mandated disclaimers and compulsory statements, constitutes compelled commercial speech, subject to First Amendment protection. Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 1996). Likewise, advertising and other marketing practices are also afforded protection as commercial speech. *See* Western States, 122 S. Ct. 1497 (advertising of compounded drugs); 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484 (1996) (advertising price of alcoholic beverages); Central Hudson, 447 U.S. 557 (promotional advertising by electrical utility); and Virginia Bd. of Pharmacy, 425 U.S. 748 (advertising by pharmacists).

In both of these situations – advertising and labeling – the current analysis employed by the Supreme Court is derived from Central Hudson, and amplified in Western States. It directs that a four-part test be utilized to evaluate whether the First Amendment has been infringed:

> If the speech concerns lawful activity and is not misleading, however, we next ask "whether the asserted governmental interest is substantial." If it is, then we determine whether the regulation directly advances the governmental interest asserted," and finally, "whether it is not more extensive than is necessary to serve that interest." Each of these latter three inquiries must be answered in the affirmative for the regulation to be found constitutional[1]. [citations omitted]

Western States, 122 S. Ct at 1504. In Western States, the Court made clear that the government's burden under the final prong is more than merely a reasonable relationship between the government interest and the restriction imposed.[2] "[I]f the Government could achieve its interests in a manner that does not restrict speech or that restricts less speech, the Government must do so." *Id.* at 1506. Likewise, "[I]f the First Amendment means anything, it means that regulating speech must be a last – not first – resort." *Id.* at 1507.

With that test in mind, CHPA now raises particular areas where the agency's current pronouncements on labeling are apt to run afoul of First Amendment legal doctrine.[3]

II. FDA's Exclusivity Policy for OTC Drug Labeling Impermissibly Compels Precise Labeling Statements In A Manner More Restrictive Than Necessary to Achieve its Governmental Interest.

In 1986, FDA issued a final rule relaxing its "exclusivity policy" with respect to OTC labeling. 51 Fed. Reg. 16258-67 (May 1, 1986) (codified at 21 C.F.R. § 330.1(c)(2)). The "flexibility" regulation replaced a proposal that would have prescribed mandatory language for *all* aspects of OTC drug labeling as the "exclusive" means by which to comply with the statutory labeling requirements. The 1986 rule allows a degree of flexibility with respect to specific wording of permissible "indications" (i.e., approved uses for the product) that may appear on OTC drug labeling. It permits either: 1) the specific wording for indications of use established in the appropriate OTC monograph; or 2) other wording describing those indications that do not offend the statutory prohibitions against false or misleading labeling; or 3) a combination of the two.

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[2] Prior to Western States, the Court had seemed to suggest that Central Hudson demanded a "reasonable fit" between means and ends, not that it impose the least restrictive requirement. *See* Bd. of Trustees of the State Univ. of New York v. Fox, 447, U.S. 469 (1989). However, Western States does indeed require more than a reasonable basis for restricting commercial speech.

[3] Restrictions on advertising of OTC drugs and dietary supplements are not addressed in these comments because memorandum of understanding between FDA and the Federal Trade Commission (FTC) places enforcement of OTC drug advertising in the jurisdiction of that agency. Likewise, the regulation of dietary supplement advertising resides with FTC. The FTC's guidelines for substantiation of truthful and not misleading advertising strikes a proper balance between the First Amendment and consumer protection. *See* Dietary Supplements: An Advertising Guide for Industry, FTC Bureau of Consumer Protection (1998).

However, the preamble of that rulemaking makes clear that "[a]ll required OTC drug labeling other than the indications for use (e.g., statement of identity, warnings and directions) must appear in the specific wording established under an OTC monograph." 51 Fed. Reg. at 16258. Today, the terminology and phraseology employed in the agency's official monographs is deemed to be the exclusive manner by which to comply with FDA's other labeling requirements.[4]

Although the so-called "flexibility policy" has been helpful to the industry with respect to alternative truthful and non-misleading wording for indications, it is unclear why FDA does not view this flexibility as extending to any other aspects of labeling – the statements of identity, for example, and instead still applies the exclusivity policy to them. Certainly the protections afforded to commercial speech apply just as much to statements of identity as they do to indications, since statements of identity are in effect shorthand versions of indications. The analysis of Western States raises questions about the constitutionality of these inflexible label demands. Western States requires that "if the Government could achieve its interests in a manner that does not restrict speech or that restricts less speech, the Government must do so. 122 S. Ct. at 1506.

In 1986, the FDA acknowledged that a less rigid policy would achieve its interest when it wrote with respect to relaxing the "Indications" portion of the label that "the goal of ensuring truthful, non-misleading labeling without inhibiting effective consumer communication does not require continuation of a rigid exclusivity policy." 51 Fed. Reg. at 16261. The agency even conceded that the industry might be better at writing label copy than FDA. "A principle impetus behind the present rulemaking was the belief that there may be many ways of fairly and accurately stating the same information. A manufacturer may well find that consumers prefer the language it develops over the 'FDA Approved' language." *Id.* at 16261-62.

The language in a monograph might appropriately serve as a benchmark by which to measure the accuracy, completeness, and comprehensibility of statements of identity, for example, as it does now in the "Indications" context. However, FDA's continuation of the rigid exclusivity policy at least for statements of identity, and perhaps other aspects of OTC labeling, as the *only* acceptable manner by which manufacturers can communicate drug information to consumers – raises Constitutional questions.

In 1986, FDA responded to the Constitutional questions raised about the exclusivity policy by commenting that even though OTC drug labeling is commercial speech with a special public health function, in cases involving public health and safety, additional restrictions on commercial speech may pass constitutional scrutiny. *Id.* at 1621, citing Central Hudson. The agency correctly noted that other restrictions may be imposed when there is a legitimate and substantial interest to be achieved, but it completely failed to address the final prong on Central Hudson (now clarified in Western States), that the restriction imposed be no more extensive than is necessary to serve that interest.

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[4] 331 C.F.R.§ 330.1 (c)(2) states: Any other labeling under this subchapter and subchapter C *et seq.* of this chapter shall be stated in the exact language where exact language has been established and identified by quotation marks in an application OTC drug monograph or by regulation . . ."

In recent cases addressing this final prong, the Court has made clear that if the Government could achieve its interest in a manner that does not restrict speech, or that restricts less speech, the Government must do so. Western States, 122 S. Ct. at 1506, *see also* Rubin v. Coors Brewing Co., 514 U.S. 476 (1995) (invalidating a law that prohibited beer labels from displaying alcohol content). Why, if the less restrictive flexibility policy announced in 1986 is permitted for the indications section of the label, and FDA concedes that this less rigid approach can achieve its desired ends, is the more restrictive exclusivity policy still necessary to achieve the governmental interest for statements of identity, for example?

Another example of inflexibility in agency rulemaking is the FDA's final rule on "Drug Facts" labeling, issued in 1999. 64 Fed. Reg. 13254 (March 17, 1999) codified at 21 C.F.R. § 201.66. That regulation prescribes not the content, but the presentation of OTC labeling information, specifying such things as permissible type size, type style, use of a bulleted format, borders, columns, heading labels, the size, shape and color of bullets, barlines and column separators. Thus, under the Drug Facts rule, a drug product could be subject to regulatory action and deemed to be misbranded if, among other things: (a) running text is used instead of bulleted lists, (b) barlines and hairlines in the Drug Facts Box depart from the prescribed thickness, (c) bullets do not meet the prescribed shape, or (d) titles or headings are centered rather than left justified. 21 CFR § 201.66 (d) and (g) (2001). If a company wishes to depart from these requirements, it must first submit an exemption/deferral petition to FDA. A substantial governmental interest can certainly be made for requiring OTC drug labeling that is truthful, not misleading and complete. However, it is questionable whether strict adherence to each and every one of these format requirements would survive a First Amendment challenge as being no more extensive than is necessary to serve this interest.

III. The Discrepancy Between Required Labeling of Dietary Supplement and Conventional Foods for the Identical Ingredients of Nutritive Value Violates the First Amendment.

In its May 16th *Federal Register* notice, FDA asks whether it may distinguish between claims concerning conventional foods and those relating to dietary supplements. In some respects, the answer to this question hinges on the statutory authority accorded to the agency by Congress under the FD&C Act, and its amendments rather than on the issue of a First Amendment right. The Dietary Supplement Health & Education Act (DSHEA) expressly requires that dietary supplements, for regulatory purposes, are to be treated as "foods" and thus, the Congressional mandate is clear.[5]

However, to the extent DSHEA permits FDA to exercise its own administrative judgment to distinguish between the permissibility of claims – permitting certain claims for conventional foods but restricting their use on dietary supplements – certainly, the holding of Western States may have implications for such determinations as well. Does a more restrictive limitation on speech with respect to dietary supplements (as compared to a lesser requirement for conventional

[5] "Except for purposes of section 201(g), a dietary supplement shall be deemed a food within the meaning of the [Food Drug & Cosmetic] Act." 21 U.S.C. § 321(ff).

food having the same nutrients) directly advance a substantial governmental interest? Is the more restrictive requirement for dietary supplements necessary to serve that interest?

One such suspect demarcation is the announcement on January 6, 2000 of final regulations on "Statements Made for Dietary Supplements Concerning the Effect of the Product on the Structure or Function of the Body." 65 Fed. Reg. 999 (Jan. 6, 2000). In that publication, FDA took the position that dietary supplements having nutritive value could not make structure/function claims under Section 201(g)(1)(C) of the FD&C Act on a parity basis with conventional foods, but could only make such claims subject to the disclaimer provided in Section 403(r)(6)[6]. CHPA, along with other organizations, petitioned for reconsideration and a stay of action on the final rule in February 2000. CHPA cited, among other reasons, a violation of the plain language of the FD&C Act, a reversal of longstanding legal precedent under the Act in violation of the Administrative Procedures Act, and policy grounds that will create consumer confusion from the inconsistent labeling applied to the same nutrients depending on whether they are found in dietary supplements or conventional foods.

To date, FDA had failed to respond to that petition or the supplemental comments filed by CHPA in December 2000. Now, against the backdrop of the Western States decision, certain constitutional concerns with respect to that final rule are raised as well. "[I]f the First Amendment means anything, it means that regulating speech must be a last – not first – resort. Yet, here, it seems to have been the first strategy the Government thought to try." Western States, 122 S. Ct. at 1507. If the governmental interest can be served without the disclaimer language of section 403(r)(6)(C) with respect to conventional foods, why is the more restrictive requirement imposed with respect to dietary supplements? Certainly the burden should be on FDA to demonstrate the need to interfere with commercial speech – but FDA has been silent on that point.

If FDA does eventually respond to this petition and provide the reasoned explanation for the reversal of its long-held position,[7] it will be hard pressed to meet the Central Hudson standard. It is hard to see how the 403(r)(6)(C) disclaimer that FDA would impose on all dietary supplements (even those having nutritive value) narrowly and appropriately advances a government interest. Under that final rule, a conventional food fortified with a particular nutrient can avoid the disclaimer requirement altogether, but a dietary supplement having the identical ingredient of nutritive value must inform consumers that the claim in its labeling "has not been evaluated by the Food & Drug Administration." This lack of parity for dietary supplements

[6] FDA's pronouncement would permit all food products having nutritive value other than those identified as a dietary supplement to make structure/function claims on their labeling without reciting the disclaimer in section 403(r)(6) of the Act (21 U.S.C. § 343(r)(6)). By contrast, dietary supplements containing the same nutritive ingredient and seeking to make the identical labeling claim would be required to state "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease." One such case is products containing calcium: a conventional food fortified with calcium may simply state, "Calcium helps to build strong bones," without further qualification, but if a dietary supplement containing calcium makes the identical statement on its labeling, it must include the disclaimer.

[7] Already, the agency shoulders a heavy burden to justify its change in policy, with respect to the requirements of the Administrative Procedure Act, a burden beyond that which may be required when the agency does not act in the first instance, *see* Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co., 463 U.S. 29, 41-42 (1983).

demonstrates the lack of precision of the rule if, indeed, the government's interest in protecting the public health with respect to exposure to certain nutrients is being addressed.

Given that these labeling claims are unquestionably a form of protected commercial speech, FDA's implementation of DSHEA in a manner that creates disparity between its review of structure/function claims for dietary supplements vs. the same claims for the same ingredient found in a conventional food is inherently suspect.

IV. In situations in which FDA regulations impose mandatory requirements or restrictions on labeling, or in other areas implicating the First Amendment, the agency should impose on itself a "substantial evidence" mandate to assure that its restrictions will satisfy *Western States*.

For a number of years, CHPA has urged FDA to adopt on its own, or for Congress to impose on it by statute, a so-called "substantial evidence rule" for FDA rulemakings. [8] The legislative history of the 1938 act strongly indicates that Congress did not mean to confer substantive rulemaking authority on FDA through the informal rulemaking process found in section 701(a).[9] Nevertheless, the agency has relied solely upon its informal rulemaking authority in section 701(a) for the promulgation of such sweeping rules as the OTC Drug Review, a far-reaching regulatory listing of approved ingredients and required labeling for every category of OTC drug, 21 C.F.R § 330-358, and the OTC label format rule, which mandates how that information is presented on labeling, including type size, type style, format, the order of information. 21 C.F.R. § 201.66.

Both of these regulations, along with others that either compel statements in labeling or prohibit certain statements in labeling, restrict the commercial speech of drug and dietary supplement manufacturers and packagers without the agency providing substantial evidence in support of its restrictions. If the second and third prongs of Central Hudson mean anything, it should be that the "arbitrary and capricious" standard, which might suffice in an informal rulemaking that does not implicate the First Amendment, is not sufficient to support regulations infringing on protected speech. Such restrictions must directly advance the governmental interest asserted and not be "more extensive than is necessary to serve that interest." Western States at 1504.

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[8] Under this standard, the agency would be required to have at least "substantial evidence" to support its substantive rules. Congress made clear in the passage of the 1938 FD&CA that formal rulemakings by the agency "shall be based only on substantial evidence of record and set forth in detailed findings of fact on which the order is based." Food, Drug & Cosmetic Act § 701(e)(3), codified at 21 U.S.C. § 371(e)(3). For many years, it was generally understood that the section 701(a) applied only to the issuance of interpretative rules, with substantive authority limited to section 701(e). However, what has transpired more recently is that the agency has increasingly relied on its informal rulemaking authority under 701(a), which permits FDA to "promulgate regulations for the efficient enforcement of this Act" but did not stipulate any particular standard of review. Thus, the agency has argued that such rulemakings are subject only to the far more deferential "arbitrary and capricious" standard of legal review.

[9] Under the formal rulemaking provision, it is clear that Congress intended to give FDA the power to issue biding substantive rules with the force and effect of law. Analysis of the legislative history, however, strongly indicates that Congress did not mean to confer similar substantive rulemaking authority on FDA in Section 701 (a). House Hearings on S. 5, 74th Cong. *reprinted in* Charles Wesley Dunn, "Federal Food, Drug and Cosmetic Act, A Statement of Its Legislative Record" 1268 (1938); *see generally* Richard A. Merrill, "FDA and the Effects of Substantive Rules," 35 Food, Drug & Cosm. L.J. 270 (1980).

Of course, the OTC label format rule and the OTC Review have not been challenged under the First Amendment. However, given that labeling is protected commercial speech, one wonders how the "arbitrary and capricious" threshold asserted by the agency as the permissible justification for these rulemakings would hold up to the Western States analysis.

For example, the OTC label format rule imposed sweeping changes that standardized the appearance of virtually every OTC drug label. It includes a prescribed type size that differs from the requirements for prescription drugs, cosmetics, dietary supplements and other products regulated by FDA. Yet, the entire evidentiary basis for this disparate treatment was two studies, one of which addressed letter compression, not type size, and the other that tested the old, textual labels at various font sizes, but not the new bulleted format. *See* 64 Fed. Reg. at 13,264-65.

No one would question that some standards in this area fulfill the statutory mandate that information on OTC drug labeling must be "prominent and conspicuous," *see* 63 U.S.C. §352(c), or that assuring readable medicine labels serves a substantial governmental interest. However, it is also clear that such a sparse evidentiary record on which FDA based the specific requirements utterly fails to demonstrate whether those particular requirements directly advance that interest or whether the requirement is "more extensive than is necessary to serve that interest." Nothing in the regulatory record nor in the statute itself suggests that the "prominent and conspicuous" standard can be satisfied *only* by imposition of a single, inflexible type size, much less the additional requirements for type style, shape and color of bullets, barlines, hairlines and column separators. After Western States, should the label format requirements come under constitutional scrutiny, they would not likely survive.

As this example demonstrates, FDA has refused to exercise restraint in promulgating its regulations that affect labeling and other forms of protected speech. It has bypassed its substantive rulemaking authority conferred by section 701(e) and opted instead to promulgate even the most sweeping of regulatory changes under its informal authority found in 701(a). Although this route makes promulgation of rules easier for the agency in the short term, the result is a legacy of regulations having profound impact on commercial speech entitled to First Amendment protection, and yet completely lacking the evidentiary justification to stand up to scrutiny after Western States. FDA would do well to adopt the "substantial evidence" test as a matter of regulatory self-discipline with regard to its labeling and advertising decision making to ensure that future rulemakings will rest on more than a reasonable basis standard and will satisfy constitutional standards.

V. Recommendation & Conclusion

These comments by no means exhaust the potential pitfalls awaiting FDA after the Western States decision. Rather, as stated at the outset, this submission is intended to highlight only a few of the areas of First Amendment concern as a result of that decision that may be particularly difficult to reconcile. The concerns about FDA's exclusivity policy unsupported by evidence that broader flexibility in labeling would fail to achieve FDA's interest, the disparity created between dietary supplement and conventional food labeling with respect to identical nutrient claims, and the absence of substantial evidence to justify restrictions on protected commercial

speech in labeling all suggest that FDA prerogative to impose restrictions on commercial speech may be vastly limited under the analysis imposed by the Supreme Court.

A logical question arises from this exercise: What happens next? The agency has apparently determined that, in the wake of Western States and other recent decisions, the agency should re-evaluate its position on a number of First Amendment-related issues. This request for comments has already generated legally sound and well-reasoned views from many within the regulated community. Certainly, the receipt of comments from so many in the industry will engender much discussion and debate within FDA about the limits on its authority and the agency's prospects for success in future commercial speech litigation with respect to particular legal issues.

However, FDA's response should not stop there. CHPA urges the agency to give careful examination to the positions and principles of law articulated in these comments, and to commit its response to a *Federal Register* Notice. FDA should acknowledge its consideration of the views expressed in response to its call for comments through the same vehicle that it requested them – a published statement in the *Federal Register* – that articulates its position on First Amendment rights as they apply to matters under FDA's jurisdiction. CHPA looks forward to a public explanation and discussion from FDA with respect to the issues we and others have raised.

As always, CHPA and its members are eager to work with the agency to find the proper balance between FDA's important public health obligations and the protections afforded under the First Amendment.

Respectfully submitted,

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